

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

NANCY ANDERSON

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Plaintiff,

*

v.

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BRITE DENTAL CORPORATION d/b/a
CREATIVE DENTAL CARE, a Florida
Corporation; MOUHANNAD BUDEIR,
D.D.S.; FARDIN ZARE, D.D.S.,
THEODORE KELTS, D.D.S.; and
MERCK & CO., INC.,

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Case No. 8:07-cv-00965-JDW-EAJ

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Defendants.

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**ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC.
AND DEMAND FOR JURY TRIAL**

Defendant, Merck & Co., Inc. (“Merck”), by and through its undersigned attorneys, hereby answers those allegations of Plaintiff’s Complaint (“Complaint”) directed to it. To the extent the allegations of any paragraph are directed to other defendants, Merck is not required to respond to those allegations. To the extent a response is deemed necessary, Merck states that it denies all such allegations, except those that are specifically admitted below. Merck denies all allegations set forth in the Complaint directed at Merck except to the extent such allegations are specifically admitted below:

JURISDICTION AND VENUE

1. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 1, except for jurisdictional purposes only, admits that the amount sought exceeds the jurisdictional limits of this Court.

PARTIES

2. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 2.

3. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 3.

4. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 4.

5. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 5.

6. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 6.

7. Merck denies each and every allegation of Paragraph 7, except that Merck admits that it is registered to do business in Florida and that its principal place of business is located at One Merck Drive, Whitehouse Station, New Jersey.

8. Merck denies each and every allegation in Paragraph 8, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® and that FOSAMAX® is a prescription medication approved by the Federal Food and Drug Administration (“FDA”) for prescription in accordance with its

approved prescribing information.

9. Merck admits only that it distributed FOSAMAX® for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 9 inconsistent with that prescribing information. Except as expressly admitted herein, Merck denies the remaining allegations in Paragraph 9.

10. Merck is without knowledge as to what is meant by the phrase “substantial revenue” so the allegations in Paragraph 10 are denied.

11. Merck is without knowledge as to what is meant by “consequences” so the allegations in Paragraph 11 are denied.

12. The allegations of Paragraph 12 are a legal conclusion to which no response is required. To the extent a response is required, Merck denies each and every allegation of Paragraph 12.

SUMMARY OF THE CASE

13. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 13.

14. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 14.

15. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 15.

16. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 16.

17. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 17.

18. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 18.

19. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 19.

20. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 20.

21. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 21.

22. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 22.

23. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 23.

24. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 24.

25. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 25.

26. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 26.

27. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 27.

28. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 28.

29. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 29.

30. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 30.

31. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 31.

32. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 32.

33. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 33.

FOSAMAX FACTS

34. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 34.

35. Merck denies each and every allegation in Paragraph 35, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

36. Merck denies each and every allegation in Paragraph 36, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing

information. Merck denies any allegations in Paragraph 36 inconsistent with that prescribing information.

37. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 37 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 37 with respect to Aredia and Zometa inconsistent with that prescribing information.

38. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 38 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 38 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations in Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck denies each and every allegation of Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 42.

43. Merck denies each and every allegation of Paragraph 43.
44. Merck denies each and every allegation of Paragraph 44.
45. Merck denies each and every allegation of Paragraph 45.
46. Merck denies each and every allegation of Paragraph 46.
47. Merck denies each and every allegation in Paragraph 47, except that Merck admits that the FDA drafted an “ODS Postmarketing Safety Review,” but respectfully refers the Court to said document for its actual language and full text.
48. Merck denies each and every allegation of Paragraph 48.
49. Merck denies each and every allegation of Paragraph 49.
50. Merck denies each and every allegation of Paragraph 50.
51. Merck denies each and every allegation of Paragraph 51, except that Merck admits that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.
52. Merck denies each and every allegation of Paragraph 52.
53. Merck denies each and every allegation of Paragraph 53.
54. Merck denies each and every allegation of Paragraph 54.
55. Merck denies each and every allegation of Paragraph 55.
56. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 56.
57. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 57.
57. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

60. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 60.

61. Merck denies each and every allegation of Paragraph 61.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

MEDICAL NEGLIGENCE FACTS

The allegations contained in Paragraphs 64 – 70 are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of Paragraphs 64 – 70.

COUNT I: CLAIM AGAINST BRITE DENTAL CORPORATION d/b/a CREATIVE DENTAL CARE

The allegations contained in Paragraphs 71 – 73 are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of Paragraphs 71 – 73.

COUNT II: CLAIM AGAINST MOUHANNAD BUDEIR, D.D.S.

The allegations contained in Paragraphs 74 – 75 are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of Paragraphs 74 – 75.

COUNT III: CLAIM AGAINST FARDIN ZARE, D.D.S.

The allegations contained in Paragraphs 76 – 77 are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of Paragraphs 76 – 77.

COUNT IV: CLAIM AGAINST THEODORE KIELTS, D.D.S.

The allegations contained in Paragraphs 78 – 79 are not directed at Merck and therefore no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of Paragraphs 78 – 79.

CLAIMS AGAINST DEFENDANT MERCK & CO., INC.

80. Merck repleads its answers to Paragraphs 1 through and including 79, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

81. Merck denies each and every allegation in Paragraph 81, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck denies each and every allegation of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

COUNT V: NEGLIGENCE

86. Merck repleads its answers to Paragraphs 1 through and including 85, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

87. The allegations in Paragraph 87 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are

denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

88. Merck denies each and every allegation of Paragraph 88, including each and every allegation of subparts (a) through (f).

89. Merck denies each and every allegation of Paragraph 89.

COUNT VI: STRICT LIABILITY

90. Merck repleads its answers to Paragraphs 1 through and including 89, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

91. Merck denies each and every allegation in Paragraph 91, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

92. Merck denies each and every allegation of Paragraph 92, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

93. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 93.

94. Merck denies each and every allegation of Paragraph 94.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

COUNT VII: BREACH OF EXPRESS WARRANTY

101. Merck repleads its answers to Paragraphs 1 through and including 100, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

102. Merck denies each and every allegation of Paragraph 102, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

103. Merck denies each and every allegation of Paragraph 103.

104. Merck denies each and every allegation of Paragraph 104.

105. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

COUNT VIII: BREACH OF IMPLIED WARRANTY

107. Merck repleads its answers to Paragraphs 1 through and including 106, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

108. Merck denies each and every allegation in Paragraph 108, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

109. Merck denies each and every allegation of Paragraph 109, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

110. Merck denies each and every allegation of Paragraph 110.

111. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 111.

112. Merck denies each and every allegation of Paragraph 112.

113. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 113.

114. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 114.

115. Merck denies each and every allegation of Paragraph 115.

COUNT IX: FRAUDULENT MISREPRESENTATION

116. Merck repleads its answers to Paragraphs 1 through and including 115, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

117. Merck denies each and every allegation of Paragraph 117, including each and every allegation contained in subparts (a) and (b). Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

118. Merck denies each and every allegation of Paragraph 118.

119. Merck denies each and every allegation of Paragraph 119.

120. Merck denies each and every allegation of Paragraph 120.

121. Merck denies each and every allegation of Paragraph 121.

122. Merck denies each and every allegation of Paragraph 122.

123. Merck denies each and every allegation of Paragraph 123.

COUNT X: FRAUDULENT CONCEALMENT

124. Merck repleads its answers to Paragraphs 1 through and including 123, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

125. Merck denies each and every allegation of Paragraph 125, including each and every allegation contained in subparts (a) and (b). Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

126. Merck denies each and every allegation of Paragraph 126. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

127. Merck denies each and every allegation of Paragraph 127.

128. Merck denies each and every allegation of Paragraph 128.

129. Merck denies each and every allegation of Paragraph 129.

130. Merck denies each and every allegation of Paragraph 130.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that any one or more of the following affirmative defenses should be available to Merck in this matter. Merck, therefore, asserts said affirmative defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these affirmative defenses as it may deem appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Merck demands strict proof of all claims and allegations contained in Plaintiff's Complaint that Merck has not expressly admitted. Further answering and by way of additional defense, Merck states as follows:

FIRST AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the complaint is barred by the applicable statute of limitations and is otherwise untimely.

SECOND AFFIRMATIVE DEFENSE

The complaint fails to state a claim upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

Each and every claim asserted or raised in the complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

FOURTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

SIXTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

SEVENTH AFFIRMATIVE DEFENSE

Other persons or entities who are not parties to this suit were guilty of negligence which was the sole proximate cause of, or a contributing cause to, the damages alleged in the complaint. Merck anticipates more specific information regarding the identity and potential liability of these non-parties will be developed during discovery. Accordingly, any damages awarded should be apportioned in accordance with Florida law.

EIGHTH AFFIRMATIVE DEFENSE

The injuries and damages, if any, sustained by the Plaintiff resulted in whole or in part from her own comparative negligence and any damages recovered should be reduced accordingly.

NINTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or another manufacturer.

TENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

ELEVENTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

TWELFTH AFFIRMATIVE DEFENSE

If Plaintiff has sustained injuries or losses as alleged in the complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic

and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions, subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims for breach of warranty are also barred for lack of timely notice of breach and/or lack of privity.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under the applicable state law because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

SIXTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

SEVENTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred.

EIGHTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiff seeks punitive damages, such claim is barred because FOSAMAX® and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under comment f to Section 6 of the Restatement (Third) of Torts: Products Liability.

TWENTY-THIRD AFFIRMATIVE DEFENSE

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part by failure to mitigate damages.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred in whole or in part because Merck's conduct conforms with medical knowledge.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recovery for strict liability because Plaintiff cannot state claims founded in strict liability because, among other things, comments j and k to Section 402A of the Restatement (Second) of Torts relegates Plaintiff's claims to a negligence cause of action.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

All activities of Merck as alleged in the complaint were expressly authorized and/or regulated by a government agency. Therefore, Plaintiff's claims pertaining to unfair or deceptive practices are barred.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Florida Constitutions.

THIRTIETH AFFIRMATIVE DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability for risks, if any, resulting from any activities undertaken by Defendant, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there is a risk inherent in the product which is the subject matter of this action, then such risk, if any, is outweighed by the benefit of the product.

THIRTY-FIRST AFFIRMATIVE DEFENSE

At all times relevant herein, any product which is the subject matter of this action processed and distributed by Merck in any state in the United States was processed and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

THIRTY-SECOND AFFIRMATIVE DEFENSE

With respect to each and every purported cause of action, the acts of Merck were at all times done in good faith and without malice.

THIRTY-THIRD AFFIRMATIVE DEFENSE

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff has not suffered any actual injury or damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred under the doctrine of economic loss.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

THIRTY-NINTH AFFIRMATIVE DEFENSE

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

FORTIETH AFFIRMATIVE DEFENSE

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

FORTY-FIRST AFFIRMATIVE DEFENSE

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims of fraud are not pleaded with the required particularity.

In so much as the complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

Respectfully submitted,

/s/ Larry Hill

LARRY HILL

Florida Bar No. 173908

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Attorneys for Defendant, Merck & Co., Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic delivery pursuant to Fed. R. Civ. P. 5(b)(2)(D) to James A. Wardell, Esquire, Wardell & Quezon, P.A., 805 West Azeele Street, Tampa, FL 33606, and to Thomas Saieva, Esquire, 601 W. Swann Ave., Suite B, Tampa, FL 33606 this 12th day of June, 2007.

/s/ Larry Hill
LARRY HILL